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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/518,383 | 03/03/00 | LI | Y 1488.1220001 |

HM12/0629
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| EXAMINER |
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| BASIC | |
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| ART UNIT | PAPER NUMBER |
| 1646 | <i>C</i> |

DATE MAILED:

06/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/518,383

Applicant(s)

Li Te Ai

Examiner

Nirmal. S. Basi

Art Unit

1646

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Mar 3, 2000

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 23-116 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 23-116 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 32, 42, 54, 67, 80, 92, and 100-114, drawn to isolated polypeptide comprising SEQ ID NO:2 or fragments and variants thereof, classified in class 530, subclass 350.
- II. Claims 23-29, 31, 33-39, 41, 43-51, 53, 55-64, 66, 68-77, 79, 81-89, 91, 93-97 and 99, drawn to the polynucleotide sequence encoding the polypeptide of SEQ ID NO:2, comprising SEQ ID NO:1 or variants and fragments thereof, vectors encoding, cells containing the afore mentioned expression vectors and a method of production and recovery of said protein from said cells, classified in class 536, subclass 23.1, for example .

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III. Claims 115, drawn to antibody that binds to the polypeptide of claim 1, classified in class 530, subclass 387.9, for example.

IV. Claims 30, 40, 52, 65, 78, 90, 98 drawn to a method for using the cell of Group II to produce the polypeptide encoded by the polynucleotide, and screen for ligand binding, classified in class 435, subclass 7.1.

V. Claim 116, drawn to an antagonist of the polypeptide of claim 111, class and subclass can not be determined because the antagonist has not been disclosed.

The inventions are distinct, each from the other because of the following reasons:

The proteins of Invention I are related to the nucleic acids of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization.

The proteins of Invention I are related to antibodies of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary steric complementary of the two, they are distinct

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inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right or in assays for the identification of agonists of the receptor protein.

5 The proteins Inventions I and the methods of Inventions IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins may be used
10 for the production of antibodies of Invention III.

 The cells Inventions II and the methods of Inventions IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different
15 process of using that product (MPEP § 806.05(h)). In the instant case the cells may be used for the production of protein which can be used to produce the antibodies of Invention III.

 The products of Invention III and V are distinct from the method of Invention IV wherein the products of Invention III and V can neither be used in nor made by the method of Invention IV.

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The products of Inventions I-III and V are distinct from each other because they have distinct functional, chemical and physical properties, and are capable of separate use and manufacture.

Because these inventions are distinct for the reasons given above and have acquired a
5 separate status in the art, restriction for examination purposes as indicated is proper. A search of the art for Inventions I-V would not be co-extensive with each other. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

10 A telephone call was made to Elizabeth Haanes on 6/19/01 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15 Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

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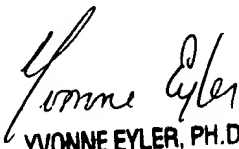
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

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Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

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Nirmal S. Basi
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June 22, 2001


YVONNE EYLER, PH.D
SUPERVISORY PATENT
TECHNOLOGY